

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/21769

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68; C07H 21/02, 21/04

US CL : 435/6; 536/23.1, 23.5

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6; 536/23.1, 23.5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

USPT, DWPI, MEDLINE, CAPLUS, LIFESCI, SCISEARCH, BIOSIS, EMBASE

search terms: interleukin 10, IL10, promoter, allele, polymorphism, mutation, SNP, genotype, -3575, -2849, -2763

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AHERN, H. Biochemical, reagent kits offer scientists good return on investment. <i>The Scientist</i> . 24 July 1995, Vol. 9, No. 15, p. 20, especially p. 3/5-4/5.	9
X	ESKDALE et al. Mapping of the human IL10 gene and further characterization of the 5' flanking sequence. <i>Immunogenetics</i> . August 1997, Vol. 46, No. 2, pages 120-128, especially Fig. 1, Fig. 4.	1, 10
Y		9
A		2-8, 11
X	MOK et al. Interleukin-10 promoter polymorphisms in southern Chinese patients with systematic lupus erythematosus. <i>Arthritis & Rheumatism</i> . June 1998, Vol. 41, No. 6, pages 1090-1095, especially Table 3.	3, 7-8
Y		9
A		1-2, 4-6, 10-11



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

26 SEPTEMBER 2000

Date of mailing of the international search report

24 OCT 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

DIANA B. JOHANSEN

Telephone No. (703) 308-0196

INTERNATIONAL SEARCH REPORT

 International application No.
 PCT/US00/21769

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y ----- A	<i>ROOD et al. Neuropsychiatric systemic lupus erythematosus is associated with imbalance in interleukin 10 promoter haplotypes. Ann. Rheum. Dis. February 1999, Vol. 58, No. 2, pages 85-89, especially p. 87-88.</i>	3, 7-8 ----- 9 ----- 1-2, 4-6, 10-11
A	<i>COAKLEY et al. Interleukin-10 promoter polymorphisms in rheumatoid arthritis and Felty's syndrome. Brit. J. Rheum. September 1998, Vol. 37, No. 9, pages 988-991.</i>	1-11
A	<i>MYTILINEOS et al. A PCR-SSP method for the detection of polymorphisms in the promoter regions of IL10, TNFA, and TGFB genes. Human Immunol. April 1999, Vol. 60, No. SUPPL 1, page S104.</i>	1-11
A	<i>KEIJRSERS et al. IL10 polymorphisms in relation to production and rheumatoid arthritis. Arthritis & Rheumatism. September 1997, Vol. 40, No. 9 SUPPL, page S179.</i>	1-11
A	<i>TOUNTAS et al. Ethnic association of 3 polymorphisms in the IL-10 promoter and inflammatory bowel disease (IBD). Gastroenterology. April 1999, Vol. 116, No. 4, Part 2, page G3617.</i>	1-11

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 10 July 2001 (10.07.01)	
International application No. PCT/US00/21769	Applicant's or agent's file reference UAB-16852/22
International filing date (day/month/year) 09 August 2000 (09.08.00)	Priority date (day/month/year) 09 August 1999 (09.08.99)
Applicant KIMBERLY, Robert, P. et al	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

05 March 2001 (05.03.01)

in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer H. Zhou Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: ELLEN S. COGEN
GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON
& CITKOWSKI, P.C.
280 N. OLD WOODWARD AVE., STE 400
BIRMINGHAM, MI 48009
US

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference UAB-16852/22	Date of Mailing (day/month/year) 24 OCT 2000
International application No. PCT/US00/21769	International filing date (day/month/year) 09 AUGUST 2000
Applicant UAB RESEARCH FOUNDATION	

*Response out 11-24-00
due 12-24-00*

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland
 Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer DIANA E. JOHANNSEN
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0125

Form PCT/ISA/220 (July 1998)*

RECEIVED
OCT 26 2000
 GIFFORD, KRASS, GROH, SPRINKLE,
 ANDERSON & CITKOWSKI, P.C.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: ELLEN S. COGEN
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Applicant's or agent's file reference UAB-16852/22	Date of Mailing <i>(day/month/year)</i> <div style="float: right; font-size: 1.2em; font-weight: bold;">24 OCT 2000</div>
International application No. PCT/US00/21769	International filing date <i>(day/month/year)</i> 09 AUGUST 2000
Applicant UAB RESEARCH FOUNDATION	

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Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer: <div style="text-align: center;"> DIANA E. JOHANNSEN </div> Telephone No. (703) 308-0196
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference UAB-16852/22	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US00/21769	International filing date (day/month/year) 09 AUGUST 2000	(Earliest) Priority Date (day/month/year) 09 AUGUST 1999
Applicant UAB RESEARCH FOUNDATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 3

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

NEW ABSTRACT

A process and a package for identifying single nucleotide polymorphisms in interleukin-10 (IL-10) are useful in identifying individual susceptibility to a disease. IL-10 is active in the immune response and autoimmune diseases. The susceptibility and severability of autoimmune disease is determined by genotyping or phenotyping an individual IL-10 promoter region. Figure 3 is a graph showing association of -3575A/-2763A SNP haplotype with production of IL-10 by donors, segregated by distal SNP haplotypes.

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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USPT, DWPI, MEDLINE, CAPLUS, LIFESCI, SCISEARCH, BIOSIS, EMBASE

search terms: interleukin 10, IL10, promoter, allele, polymorphism, mutation, SNP, genotype, -3575, -2849, -2763

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	ESKDALE et al. Mapping of the human IL10 gene and further characterization of the 5' flanking sequence. <i>Immunogenetics</i> . August 1997, Vol. 46, No. 2, pages 120-128, especially Fig. 1, Fig. 4.	1, 10
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A		2-8, 11
X	MOK et al. Interleukin-10 promoter polymorphisms in southern Chinese patients with systematic lupus erythematosus. <i>Arthritis & Rheumatism</i> . June 1998, Vol. 41, No. 6, pages 1090-1095, especially Table 3.	3, 7-8
Y		9
A		1-2, 4-6, 10-11

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

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INTERNATIONAL SEARCH REPORT

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